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Original Research Article

Use of Foot Pumps Following Total Knee Replacement as a Prophylaxis of Venous Thromboembolism: A Prospective Study.

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Abstract

Purpose: The purpose of this study was to evaluate foot pumps as mechanical prophylaxis for deep vein thrombosis (DVT) following total knee replacement (TKR).

Methods: All consecutive patients following TKR during 2017-2023 received routine duplex ultrasound surveillance for DVT 9 days postoperatively. The demographic data and risk factors were recorded. No medication was given for DVT prophylaxis in all patients.

Results: We evaluated 91 consecutive TKRs in 85 patients. Although 44 knee replacements (Group 1) done before December 2019 were not given foot pumps, 47 knee replacements (Group 2) done afterwards were given foot pumps. All patients were followed up for more than 6 months. DVT was detected in three cases (6.8%) in Group 1 compared with four knees (8.5%) in Group 2. Proximal thrombosis was observed in two knees (4.5%) in Group 1 compared with two knees (4.3%) in Group 2. No patient had pulmonary embolism. Six out of 59 (10.2%) patients who underwent the operations under general anaesthesia suffered from DVT, whereas one in 28 (3.6%) patients operated under spinal anaesthesia had DVT. All had no statistical significance.

Conclusion: The rate of proximal DVT after TKR was low (4.5%) without pharmacological prophylaxis. We advise against the use of pharmacological prophylaxis for TKRs because of the low risk of proximal DVT and its possible bleeding complications. Foot pump did not lower the rate of DVTfurther, and its use for DVT prophylaxis in TKR is not necessary.

1. INTRODUCTION

Venous thromboembolic (VTE) disease after total knee replacement (TKR) is a common complication, ranging from 24% to 60%1e4 with significant morbidity and mortality, in western population. Different types of prophylaxis, mechanical and/or pharmacological, were used with variable success. Previous reports stated that the VTE rate was much lower in Indian population. 5e8 Low level of factor V Leiden, fibrinogen, factors VIIc and VIIIc had been postulated as the reasons. 9e11 Another aetiology may be a difference in patients' diet or lifestyle.12,13 Nowadays, with the change in diet to a more western style, there is a concern that VTE disease rate may rise. The published data on VTE disease in Indian population were still sparse. In Hong Kong, Ko et al14 reported an overall deep vein thrombosis (DVT) rate of 31% after TKR, which was very comparable to that in the western population. They recommended that prophylaxis for VTE disease should be considered. However, pharmacological prophylaxis, mostly with warfarin or low-molecular-weight heparin (LMWH), could decrease the rates only to 15e30%15e18 and it was associated with a major bleeding rate of about 3e7%.19,20 The bleeding risk can be disastrous in patients receiving spinal or epidural anaesthesia. Mechanical devices such as graduated pressure compression stockings, calf compression device, and foot pumps were also used with some success, although not to the extent of pharmacological prophylaxis. 21,22 However, in a meta-analysis study,23 pneumatic compression device group had a lower DVT and an asymptomatic pulmonary embolism (PE) rate of 17% and 6.3%, respectively. The advantage of avoiding bleeding complication made them attractive,but patient compliance was a concern.The purpose of this study was to find out the DVT rate in Indian patients after TKR without pharmacologicalprophylaxis and any change after the application of foot pumps.

2. MATERIALS AND METHODS

Since August 2019, all patients after undergoing TKR in our were routinely screened by duplex ultrasound scanning on Day 9 after surgery. This study consisted of 91 consecutive primary TKRs in 85 patients from

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August 2019 to feb 2023 in two consecutive cohorts. The patients' demographic data were summarized in Table 1. No patient enrolled in the study had a history of DVT or undergone hormone replacement. No pharmacological prophylaxis was given. Aspirin or other nonsteroid anti-inflammatory drugs were stopped 2 weeks before the operation unless special advice from physician. The first 44 TKRs performed during August 2019 to December 2020 constituted Group 1. No foot pump was given. Group 2 consisted of 47 TKRs performed during December 2020 to feb 2023. They were given foot pumps (A-V Impulse System, Orthofix, Vascular, Novamedic, England) as a mechanical device for DVT prophylaxis for 5 days after the operation.

Table1: Demographic data of the patients.

	Group 1 (no foot pump)	Group 2 (foot pump)
Mean age (y)	67.8	68.4
Mean weight (kg)	77.0	65.1
Male:female ratio (no. of patients)	12:32	17:30

The foot pumps were used when patients were in bed. In both groups, graduated pressure elastic stockings were worn for 6 weeks in the postoperative period. All the operations were performed under the supervision of the same total joint consultant surgeon, with the same setting, method, and implants (nextgen posterior stabilized knee, Zimmer, depuy, Meril). Tourniquets were used during the operation to control bleeding. Suction drainage was used and removed 2 days after the operation. Walking exercise was then started. Patients were closely monitored for the symptoms and signs of VTE, which included fever, pain in the thigh or calves, prominence of the superficial veins, ankle oedema, increased warmth over the leg and ankle compared with the other side, and Homan's sign. Routine compression and duplex two-coloured Doppler ultrasound scanning (model: ATL HDI 5000 by Philips Medical) of both lower limbs were performed at Day 9 after the operation. Linear array transducers (4e7 MHz) with Doppler component were used to study the common femoral vein, superficial femoral vein, popliteal vein, and proximal leg veins. DVT was diagnosed when there was direct visualization of the thrombus in the vein, and/or the vein could not be collapsed easily and completely upon compression by the transducer with absent/diminished venous flow in the duplex scan. Once DVT was detected, an effort was made to distinguish between acute and chronic thrombosis. DVT was excluded when no filling defect was found in the veins that could be totally compressed, and a normal venous flow was demonstrated with or without augmentation. The patients were closely monitored for clinical features of DVT for 2weeks until discharge. Proximal DVT is defined as popliteal or more proximal veins. Distal DVT is thrombosis in the calf veins.When proximal DVT was diagnosed, anticoagulation was started immediately with LMWH and then with a titrated dose of warfarin for 6 months. Distal DVT was not treated but monitored radiologically by follow-up ultrasound scanning. When the clot persisted or propagated, anticoagulation would be given for 6 months as usual. Any further hospitalization for DVT/PE to any public hospital was noted through an electronic patient record system of the Hospital Authority.The patients' age, sex, medical diseases, and type of anaesthesia were analysed statistically. Patients of Groups 1 and 2 were compared. Student ttest and crosstab analysis were used. Continuous variables were expressed as mean and categorical variables were expressed as frequency. Continuous variables were compared using two sample ttests while Chi-square test was used for categorical variables.

3. RESULTS

The overall DVT rate was 7.7% (seven out of 91 TKRs). DVT was detected in 6.8% (three out of 44 TKRs) in Group 1 compared with 8.5% (four out of 47 TKRs) in Group 2. Proximal thrombosis rate was 4.4% (four out of 91 cases), including two cases (4.5%) in Group 1 and two cases (4.3%) in Group 2. Distal thrombosis was observed in one case (2.3%) in Group 1 compared with two cases (4.3%) in Group 2. No statistical difference was found. No patient in either group had symptomatic DVT or PE. The results were summarized in Table 2. The DVT rates were analysed with different factors including age, sex, body weight, and disease. There were no statistically significant differences.Two patients died within 6 months after the operation. One patient in Group 1 died of pneumonia after being discharged from the hospital. There was no DVT on postoperative ultrasound scanning and no evidence of PE. The second patient belonged to Group 2 and was diagnosed with proximal DVT. The patient was then put on anticoagulation but, unfortunately, later died of diverticulitis and peritonitis.

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Table 2: Incidence and extent of DVT in groups 1 and 2

	Group 1 (no foot pump)	Group 2 (foot pump)	p-value
Proximal DVT (ratio to the total no. of patients)	2/44 (4.5%)	2/47 (4.3%)	0.946
Distal DVT (ratio to the total no. of patients)	1/44 (2.3%)	2/47 (4.3%)	0.597
Overall DVT (ratio to the total no. of patients)	3/44 (6.8%)	4/47 (8.5%)	0.762

Considering the type of anaesthesia used, spinal anaesthesia (SA) was associated with a lower rate of DVT. Six out of 63 patients having TKR (9.5%), with the operations being performed under general anaesthesia (GA), developed DVT compared with one out of 28 cases (3.6%) with SA. The difference was not statistically signiicant. The crude odds ratio of having DVT, given that GA was used, was 2.842 and its 95% conidence interval was 0.326e24.792. The DVT rate was higher in GA group; however, as the value 1 was inside the interval range, it implied that the crude odds ratio was not signiicantly different from 1 at 5% level. Hence, the patients under GA were not statistically at a higher risk of getting DVT than those under SA (p value for proximal DVT was 0.946, for distal DVT 0.597, and for overall DVT 0.762).
In Group 2, 10 out of the 46 patients (22%) had stopped the foot pumps before Day 5 because of discomfort.

4. Discussion and Conclusion

Indian patients were found to have a low DVT rate. It was estimated to be 16.6 events per 100,000 populations in India. A slower and smaller increase in antithrombin III levels was suggested as one of the reasons. However, there appeared to be an increase in the incidence of VTE disease in the recent decades. A signiicant increase in the incidence of fatal PE in Indian from 0.21% in 1960s to 4.7% in 1990s was reported. Lifestyle changes, an ageing population, and increasing surgeries in high-risk patients may be the causes.12,13
In other parts of Asia, there was a large variation in reported DVT rates. Kim etal27 reported 11% and 20% DVT rates in bilateral and unilateral TKR, respectively, in 473 knees of Korean patients without pharmacological prophylaxis. All patients had venography and perfusion lung scan. No PE was found. They neither gave DVT and PE prophylaxis nor treated DVT unless patients had a symp- tomatic PE.
In western populations, DVT prophylaxis is a common practice in TKRs to prevent the potentially lethal risk of PE. But, in contrast to total hip replacement, a large proportion of the DVT after TKR was distal.28,29 The risk of proximalclot propagation and hence PE was lower.18,28
Physical and/or pharmacological means of prophylaxis were used with variable success. Physical prophylaxis does not interfere with the blood clotting ability and hence should avoid any bleeding complications. In a meta-analysis of 23 studies of 6001 patients, the pneumatic compression device group has the lowest DVT rate of 17% compared with the aspirin group (53%), warfarin group (45%), and LMWH group (23%).23 The incidence of asymptomatic PE was also lowest in the pneumatic device group (6.3%) compared with aspirin group (11.7%) and warfarin group (8.2%). No study with LMWH used routine lung scans and hence was not compared. Warwicket al30performed a comparison study between using foot pump and LMWH, and reported the DVT rate to be 58% (57/99 patients) and 54% (48/89 patients), respectively. There were four cases of proximal DVT and two cases of fatal PE in the foot-pump group, but none in the LMWH group. Predictably, there were fewer haemorrhagic complications in the foot-pump group.

On the other hand, some studies reported a lower DVT rate in the LMWH group. In a study of 108 patients, Blanchard et al31 re- ported a significantly lower DVT rate ($p < 0.001$) in the LMWH group (26.7%) than in the foot-pump group (64.6%).
A low DVT rate was found in our study of India n patients (7.7% overall and 4.4% proximal DVT). Pharmacological prophylaxis was not justified in view of the potential bleeding complications of warfarin or LMWH (major bleeding rate of 3e4%). We can use vigilant clinical surveillance and ultrasound scanning at Day 9 for routine screening. Urgent ultrasonic scanning can be arranged if symptoms and signs of DVT appear at any time.
From our result, the use of foot pumps did not provide any advantage in reducing the DVT rate. No significant difference was found in DVT rates between the groups without and with foot pumps (6.8% vs. 8.5%, respectively). Neither was a difference in proximal DVT rates found (4.5% in Group 1 vs. 4.3% in

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Group 2). In addition, 22% patients found foot pumps uncomfortable and stopped their use before the completion of 5 days. Hence, compli- ance was a problem.

In our population, SA is associated with a lower DVT rate than GA (3.6% vs. 9.5%, respectively). Although the difference was not statistically significant, this finding was reported in other studies of the western population.32 Regional anaesthesia maybe preferred to GA if feasible in order to lower the DVT rate.

One drawback of this study was the use of duplex ultrasound scanning rather than venography for the diagnosis of DVT. The accuracy may be dependent on the ultrasonologists. However, ultrasound is replacing venography for routine screening around the world because it is noninvasive and avoids the complications associated with contrast injection.

In summary, the rates of overall (7.7%) and proximal (4.4%) DVT were low in Indian population after TKRs without pharmacological prophylaxis. Foot pumps did not lower the DVT rate. In view of the low proximal DVT rate, pharmacological prophylaxis was also not recommended as the reported bleeding complication rate was close to the proximal DVT unless there were other high risk factors of DVT or PE. Regional anaesthesia may further decrease the risk of DVT.

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